

BIOLIFE SOLUTIONS INC  
Form 10-Q  
August 06, 2015

---

---

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

FORM 10-Q

☐ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF  
1934

For the quarterly period ended June 30, 2015

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE  
ACT OF 1934

For the transition period from      to

Commission File Number 0-18170

BioLife Solutions, Inc.  
(Exact name of registrant as specified in its charter)

DELAWARE  
(State or other jurisdiction of  
incorporation or organization)

94-3076866  
(IRS Employer  
Identification No.)

3303 MONTE VILLA PARKWAY, SUITE 310, BOTHELL, WASHINGTON, 98021  
(Address of registrant's principal executive offices, Zip Code)

(425) 402-1400  
(Telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☐ No "

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (S232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post said files). Yes ☐ No "

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer", and "smaller reporting

Edgar Filing: BIOLIFE SOLUTIONS INC - Form 10-Q

company” in Rule 12b-2 of the Exchange Act. Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

As of July 31, 2015, 12,154,858 shares of the registrant’s common stock were outstanding.

---

---

BIOLIFE SOLUTIONS, INC.

FORM 10-Q

FOR THE QUARTER ENDED JUNE 30, 2015

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1.	Consolidated Financial Statements	
	Consolidated Balance Sheets as of June 30, 2015 (unaudited) and December 31, 2014	3
	Consolidated Statements of Operations (unaudited) for the three and six month periods ended June 30, 2015 and 2014	4
	Consolidated Statements of Comprehensive Loss (unaudited) for the three and six month periods ended June 30, 2015 and 2014	5
	Consolidated Statements of Cash Flows (unaudited) for the six month periods ended June 30, 2015 and 2014	6
	Notes to Consolidated Financial Statements (unaudited)	7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	12
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	16
Item 4.	Controls and Procedures	16

PART II. OTHER INFORMATION

Item 6.	Exhibits	17
	Signatures	17
	Index to Exhibits	18

## PART I. FINANCIAL INFORMATION

## Item 1. Consolidated Financial Statements

BIOLIFE SOLUTIONS, INC.  
Consolidated Balance Sheets

(Unaudited)

	June 30, 2015	December 31, 2014
Assets		
Current assets		
Cash and cash equivalents	\$ 3,896,405	\$ 2,538,758
Short term investments	2,956,428	7,399,636
Accounts receivable, trade, net of allowance for doubtful accounts of \$0 at June 30, 2015 and December 31, 2014	809,387	901,623
Inventories	1,321,257	965,224
Prepaid expenses and other current assets	313,412	360,521
Total current assets	9,296,889	12,165,762
Property and equipment		
Leasehold improvements	1,284,491	1,284,491
Furniture and computer equipment	514,056	476,788
Manufacturing and other equipment	1,007,127	972,386
Subtotal	2,805,674	2,733,665
Less: Accumulated depreciation	(1,246,787)	(1,078,060)
Net property and equipment	1,558,887	1,655,605
Internal use software	762,860	—
Intangible asset	2,215,385	2,215,385
Long term deposits	36,166	36,166
Total assets	\$ 13,870,187	\$ 16,072,918
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	\$ 640,271	\$ 474,662
Accrued expenses and other current liabilities	62,741	121,869
Accrued compensation	326,928	535,029
Deferred rent	130,216	130,216
Total current liabilities	1,160,156	1,261,776
Long term liabilities		
Deferred rent, long term	832,976	874,825
Total liabilities	1,993,132	2,136,601
Commitments and contingencies (Note 10)		
Shareholders' equity		
Common stock, \$0.001 par value; 150,000,000 shares authorized, 12,154,858 and 12,084,859 shares issued and outstanding at June 30, 2015 and December 31, 2014	12,154	12,084
Additional paid-in capital	72,149,598	71,911,328

Edgar Filing: BIOLIFE SOLUTIONS INC - Form 10-Q

Accumulated other comprehensive loss	(1,390)	(6,448)
Accumulated deficit	(62,138,848)	(60,112,987)
Total BioLife Solutions, Inc. shareholders' equity	10,021,514	11,803,977
Total non-controlling interest equity	1,855,541	2,132,340
Total shareholders' equity	11,877,055	13,936,317
Total liabilities and shareholders' equity	\$ 13,870,187	\$ 16,072,918

The accompanying Notes to Consolidated Financial Statements are an integral part of these consolidated financial statements

BIOLIFE SOLUTIONS, INC.  
Consolidated Statements of Operations

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Product sales	\$1,496,759	\$1,211,900	\$2,997,481	\$3,276,930
Cost of product sales	678,111	666,580	1,296,210	1,828,221
Gross profit	818,648	545,320	1,701,271	1,448,709
<b>Operating expenses</b>				
Research and development	301,334	192,778	623,499	360,065
Sales and marketing	642,490	270,616	1,142,745	512,016
General and administrative	1,030,701	969,799	2,251,406	1,833,542
Total operating expenses	1,974,525	1,433,193	4,017,650	2,705,623
Operating loss	(1,155,877)	(887,873 )	(2,316,379)	(1,256,914)
<b>Other income (expenses)</b>				
Interest income	5,482	4,517	13,719	4,517
Interest expense	—	—	—	(177,308 )
Amortization of deferred financing costs	—	—	—	(13,022 )
Total other income (expenses)	5,482	4,517	13,719	(185,813 )
Net loss	(1,150,395 )	(883,356 )	(2,302,660 )	(1,442,727)
Net loss attributable to non-controlling interest	156,016	—	276,799	—
Net loss attributable to BioLife Solutions, Inc.	\$(994,379 )	\$(883,356 )	\$(2,025,861 )	\$(1,442,727)
<b>Basic and diluted net loss per common share attributable to BioLife Solutions, Inc.</b>				
	\$(0.08 )	\$(0.07 )	\$(0.17 )	\$(0.16 )
<b>Basic and diluted weighted average common shares used to calculate net loss per common share</b>				
	12,144,776	12,010,361	12,122,667	8,807,376

The accompanying Notes to Consolidated Financial Statements are an integral part of these consolidated financial statements

BIOLIFE SOLUTIONS, INC.  
Consolidated Statements of Comprehensive Loss

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Net loss	\$(1,150,395)	\$(883,356 )	\$(2,302,660)	\$(1,442,727)
Other comprehensive income (loss)				
Unrealized gain (loss) on available-for-sale investments	(441 )	(3,507 )	5,058	(3,507 )
Total other comprehensive income (loss)	(441 )	(3,507 )	5,058	(3,507 )
Comprehensive loss attributable to non-Controlling interest	156,016	—	276,799	—
Comprehensive loss attributable to BioLife Solutions, Inc.	\$(994,820 )	\$(886,863 )	\$(2,020,803)	\$(1,446,234)

The accompanying Notes to Consolidated Financial Statements are an integral part of these consolidated financial statements

BIOLIFE SOLUTIONS, INC.  
Consolidated Statements of Cash Flows

(unaudited)

	Six Month Period Ended June 30,	
	2015	2014
Cash flows from operating activities		
Net loss	\$ (2,302,660)	\$ (1,442,727)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	168,727	122,725
Stock-based compensation expense	158,371	109,176
Stock issued for services	—	150,000
Amortization of deferred financing costs	—	13,022
Amortization of deferred rent related to lease incentives	(63,500)	(80,137)
Accretion and amortization on available for sale investments	65,485	19,640
Change in operating assets and liabilities		
(Increase) Decrease in		
Accounts receivable, trade	92,236	442,776
Inventories	(356,033)	(257,232)
Prepaid expenses and other current assets	47,762	9,645
Increase (Decrease) in		
Accounts payable	(99,771)	(696,964)
Accrued compensation and other current liabilities	(267,229)	(324,423)
Accrued interest, related parties	—	177,308
Deferred rent	21,651	(10,453)
Net cash used in operating activities	(2,534,961)	(1,767,644)
Cash flows from investing activities		
Sales of available-for-sale investments	4,725,000	—
Purchases of available-for-sale investments	(342,872)	(6,065,524)
Costs associated with internal use software development	(497,480)	—
Purchase of property and equipment	(72,009)	(97,699)
Net provided by (used in) investing activities	3,812,639	(6,163,223)
Cash flows from financing activities		
Proceeds from sale of common stock, net of expenses	—	13,596,230
Proceeds from exercise of common stock options	79,969	80,592
Net cash provided by financing activities	79,969	13,676,822
Net increase in cash and cash equivalents	1,357,647	5,745,955
Cash and cash equivalents - beginning of period	2,538,758	156,273
Cash and cash equivalents - end of period	\$ 3,896,405	\$ 5,902,228
Non-cash investing activities		

Costs incurred for capitalized internal use software not paid as of quarter end (amounts are included in liabilities)	\$ 265,380	\$ —
---	------------	------

Non-cash financing activities

Conversion of notes payable and related party accrued interest to equity, net of unamortized deferred finance costs	\$	—\$ 14,180,193
---	----	----------------

The accompanying Notes to Consolidated Financial Statements are an integral part of these consolidated financial statements

BIOLIFE SOLUTIONS, INC.

Notes to Consolidated Financial Statements  
(unaudited)

1. Organization and Significant Accounting Policies

Business

BioLife Solutions, Inc. ("BioLife," "us," "we," "our," or the "Company") is the leading developer, manufacturer and marketer of proprietary clinical grade cell and tissue hypothermic storage and cryopreservation freeze media and a related cloud hosted biologistics cold chain management app for smart shippers. The Company's proprietary HypoThermosol® and CryoStor® platform of solutions are highly valued in the biobanking, drug discovery, and regenerative medicine markets. Our biopreservation media products are serum-free and protein-free, fully defined, and are formulated to reduce preservation-induced cell damage and death. The Company's enabling technology provides commercial companies and clinical researchers significant improvement in shelf life and post-preservation viability and function of cells, tissues, and organs. Additionally, for our direct, distributor, and contract customers, we perform custom formulation, fill, and finish services.

Basis of Presentation

We have prepared the accompanying unaudited consolidated financial statements pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Pursuant to these rules and regulations, we have condensed or omitted certain information and footnote disclosures we normally include in our annual consolidated financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). In management's opinion, we have made all adjustments (consisting only of normal, recurring adjustments) necessary to fairly present our financial position, results of operations and cash flows. Our interim period operating results do not necessarily indicate the results that may be expected for any other interim period or for the full year. These consolidated financial statements and accompanying notes should be read in conjunction with the financial statements and notes thereto in our Annual Report on Form 10-K for the year ended December 31, 2014 on file with the SEC.

There have been no material changes to our significant accounting policies as compared to the significant accounting policies described in the financial statements in our Annual Report on Form 10-K for the year ended December 31, 2014.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its majority-owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

Concentrations of credit risk and business risk

In the three and six months ended June 30, 2015, we derived approximately 15% and 10% of our product revenue from one customer. In the three and six months ended June 30, 2014, we derived approximately 11% and 33% of our product revenue from our relationship with one contract manufacturing customer. No other customer accounted for more than 10% of revenue in the three and six months ended June 30, 2015 or 2014. At June 30, 2015, two customers accounted for approximately 29% of total gross accounts receivable. At December 31, 2014, two customers accounted for approximately 25% of total gross accounts receivable.

Revenue from customers located in foreign countries represented 20% and 21% of total revenue during the three and six months ended June 30, 2015 and 22% and 13% during the three and six months ended June 30, 2014, respectively.

#### Internal Use Software

We capitalize costs associated with the development of the biologistex web and mobile applications, which we consider internal-use software. Capitalization of costs began in the first quarter of 2015, when we reached the application development stage. Such capitalized costs include external direct costs utilized in developing or obtaining the applications and payroll and payroll-related expenses for employees, who are directly associated with the development of the applications. Capitalization will cease once we have completed all substantial testing, at which time the applications are complete and ready for their intended use.

In the six months ended June 30, 2015, we capitalized \$0.8 million in costs related to the development of the biologistex web and mobile applications. Maintenance and enhancement costs, including those costs in the post-implementation stages, will be expensed as incurred, unless such costs relate to substantial upgrades and enhancements to the software that result in added functionality, in which case the costs are capitalized. Capitalized costs will be amortized on a straight-line basis over estimated useful life of three years once the software has been commercially deployed.

#### Recent Accounting Pronouncements

On May 28, 2014, the Financial Accounting Standards Board (“FASB”) issued ASU No. 2014-09, Revenue from Contracts with Customers, Topic 606, requiring an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The updated standard will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective and permits the use of either the retrospective or cumulative effect transition method. Early adoption is not permitted. The updated standard becomes effective for us in the first quarter of fiscal 2018. We have not yet selected a transition method and we are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

With the exception of the new revenue standard discussed above, there have been no new accounting pronouncements not yet effective that have significance, or potential significance, to our Consolidated Financial Statements.

#### 2. Accumulated Other Comprehensive Loss

The following tables show the changes in Accumulated Other Comprehensive Loss by component for the six months ended June 30, 2015:

	Six Months Ended June 30, 2015
Unrealized Loss on Investments, Beginning Balance	\$ (6,448)
Unrealized Gain on Investments, Current Period	5,058
Unrealized Loss on Investments, Ending Balance	\$ (1,390)

#### 3. Fair Value Measurement

In accordance with FASB ASC Topic 820, "Fair Value Measurements and Disclosures," (“ASC Topic 820”), the Company measures its cash and cash equivalents and short term investments at fair value on a recurring basis. ASC Topic 820 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, ASC Topic 820 establishes a three-tier value fair hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 – Observable inputs that reflect quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 – Observable inputs other than quoted prices included in Level 1 for similar assets or liabilities, quoted prices in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities.

Level 3 – Unobservable data points for the asset or liability, and include situations where there is little, if any, market activity for the asset or liability.

As of June 30, 2015 and December 31, 2014, the Company does not have liabilities that are measured at fair value.

The following tables set forth the Company's financial assets measured at fair value on a recurring basis as of June 30, 2015 and December 31, 2014, based on the three-tier fair value hierarchy:

As of June 30, 2015	Level 1	Level 2	Total
Bank deposits	\$ 644,355	\$ —	\$ 644,355
Money market funds	3,252,050	—	3,252,050
Cash and cash equivalents	3,896,405	—	3,896,405
Corporate debt securities	2,956,428	—	2,956,428
Total	\$ 6,852,833	\$ —	\$ 6,852,833

As of December 31, 2014	Level 1	Level 2	Total
Bank deposits	\$ 972,891	\$ —	\$ 972,891
Money market funds	1,565,867	—	1,565,867
Cash and cash equivalents	2,538,758	—	2,538,758
Corporate debt securities	6,799,702	—	6,799,702
Commercial paper	599,934	—	599,934
Short term investments	7,399,636	—	7,399,636
Total	\$ 9,938,394	\$ —	\$ 9,938,394

The fair values of bank deposits, money market funds, corporate debt securities and commercial paper classified as Level 1 were derived from quoted market prices as active markets for these instruments exist. The Company has no level 2 or level 3 financial assets. The Company did not have any transfers between Level 1 and Level 2 of the fair value hierarchy during the six months ended June 30, 2015 and the twelve months ended December 31, 2014.

Investments in debt securities at June 30, 2015, are investment grade and carried a long-term rating of BBB+ or higher.

#### 4. Short Term Investments

The amortized cost and fair value of short term investments as of June 30, 2015 were as follows:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate debt securities	\$ 2,957,818	\$ —	\$ (1,390)	\$ 2,956,428

The amortized cost and fair value of short term investments as of December 31, 2014 were as follows:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate debt securities	\$ 6,806,150	\$ —	\$ (6,448)	\$ 6,799,702
Commercial paper	599,934	—	—	599,934
Total marketable securities	\$ 7,406,084	\$ —	\$ (6,448)	\$ 7,399,636

As of June 30, 2015, there are no short term investments, classified and accounted for as available-for-sale securities that have been in a continuous unrealized loss position in excess of twelve months.

As of June 30, 2015, all of the Company's short term investments had maturity dates due within 1 year or less.

#### 5. Inventory

Inventory consists of the following at June 30, 2015 and December 31, 2014:

	June 30, 2015	December 31, 2014
Raw materials	\$ 290,980	\$ 362,656
Work in progress	490,026	79,012
Finished goods	540,251	523,556

Total	\$ 1,321,257	\$ 965,224
-------	--------------	------------

9

---

## 6. Deferred Rent

Deferred rent consists of the following at June 30, 2015 and December 31, 2014:

	June 30, 2015	December 31, 2014
Landlord-funded leasehold improvements	\$ 1,124,790	\$ 1,124,790
Less accumulated amortization	(312,031)	(248,531)
Total	812,759	876,259
Straight line rent adjustment	150,433	128,782
Total deferred rent	\$ 963,192	\$ 1,005,041

During the three and six month periods ended June 30, 2015, the Company recorded \$31,750 and \$63,500, respectively, in deferred rent amortization of these landlord funded leasehold improvements. During the three and six month periods ended June 30, 2014, the Company recorded \$27,063 and \$54,126, respectively, in deferred rent amortization of these landlord funded leasehold improvements.

Straight line rent adjustment represents the difference between cash rent payments and the recognition of rent expense on a straight-line basis over the terms of the lease.

## 7. Share-based Compensation

## Stock Options

We have a stock-based compensation plan, the 2013 Performance Incentive Plan (the “2013 Plan”), which allows us to grant options or restricted stock units to all employees, including executive officers, outside consultants, and non-employee directors. The Plan was amended by stockholder approval on May 4, 2015, to increase the number of shares of common stock available to be granted under the Plan to 3,100,000, plus any shares of common stock underlying any option granted pursuant to an equity compensation plan other than the 2013 Plan that was outstanding on June 20, 2013, the date the stockholders originally approved the 2013 Plan.

The following is a summary of stock option activity for the six month period ended June 30, 2015, and the status of stock options outstanding at June 30, 2015:

	Six Month Period Ended June 30, 2015	
	Options	Wtd. Avg. Exercise Price
Outstanding at beginning of year	1,390,770	\$ 1.50
Granted	1,280,881	\$ 2.06
Exercised	(69,999)	\$ 1.14
Outstanding at June 30, 2015	2,601,652	\$ 1.79
Stock options exercisable at June 30, 2015	1,214,517	\$ 1.39

As of June 30, 2015, there was \$914,103 of aggregate intrinsic value of outstanding stock options, including \$901,307 of aggregate intrinsic value of exercisable stock options. Intrinsic value is the total pretax intrinsic value for all “in-the-money” options (i.e., the difference between the Company’s closing stock price on the last trading day of the

quarter and the exercise price, multiplied by the number of shares) that would have been received by the option holders had all option holders exercised their options on June 30, 2015. This amount will change based on the fair market value of the Company's stock. During the three and six months ended June 30, 2015 intrinsic value of awards exercised was \$50,985 and \$71,922, respectively. Weighted average grant date fair value for options granted during the three and six months ended June 30, 2015 was \$1.75 per share and \$3.19 for the three and six months ended June 30, 2014.

The fair value of share-based payments made with stock options to employees and non-employee directors was estimated on the measurement date using the Black-Scholes model using the following weighted average assumptions.

	Three Month Period Ended June 30,		Six Month Period Ended June 30,	
	2015	2014	2015	2014
Risk free interest rate	1.77%	2.14%	1.77%	2.14%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected term (in years)	7	7	7	7
Volatility	105%	105%	105%	105%

We recorded stock compensation expense related to options for the three and six month periods ended June 30, 2015 and 2014, as follows:

	Three Month Period Ended June 30,		Six Month Period Ended June 30,	
	2015	2014	2015	2014
Research and development costs	\$ 19,414	\$ 9,351	\$ 26,358	\$ 17,486
Sales and marketing costs	19,270	2,563	25,025	5,286
General and administrative costs	57,677	39,111	65,450	65,276
Cost of product sales	28,501	6,532	41,538	21,128
Total	\$ 124,862	\$ 57,557	\$ 158,371	\$ 109,176

Management applies an estimated forfeiture rate that is derived from historical employee termination data. The estimated forfeiture rate applied for the three and six month periods ended June 30, 2015 and 2014 was approximately 7%.

As of June 30, 2015, we had approximately \$2,401,406 of unrecognized compensation expense related to unvested stock options. We expect to recognize this compensation expense over a weighted average period of approximately 3.6 years.

During the six months ended June 30, 2014, we issued or committed to issue common stock of the Company with a value of \$150,000 for services rendered during the period. These costs were recorded in general and administrative expenses during the period.

#### Restricted Stock

At June 30, 2015, there were no unvested restricted stock units outstanding.

#### 8. Warrants

At June 30, 2015 and December 31, 2014, we had 7,428,141 warrants outstanding and exercisable with a weighted average exercise price of \$4.49. The outstanding warrants have expiration dates between November 2015 and March 2021.

#### 9. Net Loss per Common Share

Basic net loss per common share is calculated by dividing the net loss by the weighted average number of common shares outstanding during the period. Diluted earnings per share is calculated using the weighted average number of common shares outstanding plus dilutive common stock equivalents outstanding during the period. Common stock equivalents are excluded for the three and six month periods ended June 30, 2015 and 2014, since the effect is anti-dilutive due to the Company's net losses. Common stock equivalents include stock options and warrants.

Basic weighted average common shares outstanding, and the potentially dilutive securities excluded from loss per share computations because they are anti-dilutive, are as follows as of June 30, 2015 and 2014, respectively:

	Three Month Period Ended June 30,		Six Month Period Ended June 30,	
	2015	2014	2015	2014
	12,144,776	12,010,361	12,122,667	8,807,376

Basic and diluted weighted average common stock shares  
outstanding

Potentially dilutive securities excluded from loss per share  
computations:

Common stock options	2,601,652	1,367,465	2,601,652	1,367,465
Common stock purchase warrants	7,428,141	7,428,141	7,428,141	7,428,141

## 10. Commitments & Contingencies

### Leases

We lease approximately 30,000 square feet in our Bothell, Washington headquarters. The term of our lease continues until July 31, 2021 with two options to extend the term of the lease, each of which is for an additional period of five years, with the first extension term commencing, if at all, on August 1, 2021, and the second extension term commencing, if at all, immediately following the expiration of the first extension term. In accordance with the amended lease agreement, our monthly base rent is approximately \$59,700, with scheduled annual increases each August and again in October for the most recent amendment. We are also required to pay an amount equal to the Company's proportionate share of certain taxes and operating expenses.

### Employment agreements

We have employment agreements with the Chief Executive Officer, Chief Financial Officer, Chief Technology Officer, Chief Operating Officer, Vice President, Marketing and Vice President, Global Sales. None of these employment agreements is for a definitive period, but rather each will continue indefinitely until terminated in accordance with its terms. The agreements provide for a base annual salary, payable in monthly (or shorter) installments. In addition, the agreement with the Chief Executive Officer provides for incentive bonuses at the discretion of the Board of Directors. Under certain conditions and for certain of these officers, we may be required to pay additional amounts upon terminating the officer or upon the officer resigning for good reason.

### biologistex

Our biologistex joint venture committed to purchase approximately \$2.4 million in Smart Containers from SAVSU. As of June 30, 2015, the purchase commitment is \$2.4 million.

We agreed to pay SAVSU \$1.0 million in consideration of SAVSU's participation in the biologistex joint venture. If certain performance requirements are met, these costs to SAVSU will be recorded in monthly increments for twelve months. As of June 30, 2015, we have recorded \$0.4 million related to this commitment.

### Litigation

From time to time, the Company is subject to various legal proceedings that arise in the ordinary course of business, none of which are currently material to the Company's business.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Forward Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements". These forward-looking statements involve a number of risks and uncertainties. We caution readers that any forward-looking statement is not a guarantee of future performance and that actual results could differ materially from those contained in the forward-looking statement. These statements are based on current expectations of future events. Such statements include, but are not limited to, statements about future financial and operating results, plans, objectives, expectations and intentions, costs and expenses, interest rates, outcome of contingencies, financial condition, results of operations, liquidity, business strategies, cost savings, objectives of management and other statements that are not historical facts. You can find many of these statements by looking for words like "believes," "expects," "anticipates," "estimates," "may," "should," "will," "plan," "intend," or similar expressions in this Quarterly Report on Form 10-Q. We intend that such forward-looking statements be subject to the safe harbors created thereby. Examples of these forward-looking statements include, but are not limited to:

anticipated product developments, regulatory filings and related requirements;  
timing and amount of future contractual payments, product revenue and operating expenses;  
market acceptance of our products and the estimated potential size of these markets; and  
projections regarding liquidity, capital requirements and the terms of any financing agreements.

These forward-looking statements are based on the current beliefs and expectations of our management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results may differ materially from current expectations and projections. These risks and uncertainties include those factors described in greater detail in the risk factors disclosed in our Form 10-K for the fiscal year ended December 31, 2014 filed with the SEC. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those anticipated in these forward-looking statements. The Company undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q or, in the case of documents referred to or incorporated by reference, the date of those documents.

All subsequent written or oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We do not undertake any obligation to release publicly any revisions to these forward-looking statements to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to reflect the occurrence of unanticipated events, except as may be required under applicable U.S. securities law. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

Overview

Management's discussion and analysis provides additional insight into the Company and is provided as a supplement to, and should be read in conjunction with, our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 filed with the SEC.

We were incorporated in Delaware in 1987 under the name Trans Time Medical Products, Inc. In 2002, the Company, then known as Cryomedical Sciences, Inc., and engaged in manufacturing and marketing cryosurgical products, completed a merger with our wholly-owned subsidiary, BioLife Solutions, Inc., which was engaged as a developer and marketer of biopreservation media products for cells and tissues. Following the merger, we changed our name to BioLife Solutions, Inc. We have one majority-owned subsidiary, biologistex CCM, LLC, a Delaware limited liability company.

Our proprietary, clinical grade HypoThermosol® FRS and CryoStor® biopreservation media products are marketed to the regenerative medicine, biobanking and drug discovery markets, including hospital-based stem cell transplant centers, pharmaceutical companies, cord blood and adult stem cell banks, hair transplant centers, and suppliers of cells to the drug discovery, toxicology testing and diagnostic markets. All of our biopreservation media products are serum-free and protein-free, fully defined, and are manufactured under current Good Manufacturing Practices (cGMP) using United States Pharmacopodia (USP)/Multicompendial or the highest available grade components.

Our patented biopreservation media products are formulated to reduce preservation-induced, delayed-onset cell damage and death. Our platform enabling technology provides our customers significant shelf life extension of biologic source material and final cell products, and also greatly improved post-preservation cell, tissue, and organ viability and function.

The discoveries made by our scientists and consultants relate to how cells, tissues, and organs respond to the stress of hypothermic storage, cryopreservation, and the thawing process. These discoveries enabled the formulation of innovative biopreservation media products that protect biologic material from preservation-related cellular injury, much of which is not apparent immediately after return to normothermic body temperature. Our product formulations have demonstrated notable reduction in apoptotic (programmed) and necrotic (pathologic) cell death mechanisms and are enabling the clinical and commercial development of dozens of innovative regenerative medicine products.

On September 29, 2014, we entered into a limited liability company agreement with SAVSU Technologies, LLC, a Delaware limited liability company, to create a 20-year joint venture for the purpose of acquiring, developing, maintaining, owning, operating, marketing and selling an integrated platform of a cloud-based information service and precision thermal shipping products. The evo™ line is our new line of “smart shippers” designed for the shipment of materials, which must be maintained frozen, at 2-8°C and/or controlled room temperature temperatures and where near real time monitoring of temperature, location, and payload status information is necessary. A sophisticated electronics package embedded in the evo provides streaming data to the biologistex web-based application; where real time shipment status, history, and reports can be generated. Designed for small volume shipments; it fills a critical need in chain-of-custody scenarios for temperature sensitive shipments of cells, tissues, and other cell based products.

#### Highlights for the Second Quarter of 2015

Proprietary products revenue was \$1.4 million in the second quarter of 2015, an increase of 33% over the same period in 2014. For the first six months of 2015, proprietary products revenue increased 32% as compared to last year. Second quarter revenue growth drivers include increased sales of CryoStor and HypoThermosol biopreservation media to the regenerative medicine segment and continued strong product demand from BioLife’s indirect sales channel, where the Company’s products are distributed by STEMCELL Technologies, VWR, Thermo Fisher Scientific, Sigma Aldrich and a number of international distribution companies.

Gross margin in the second quarter of 2015 was 55%, compared to 45% in the second quarter of 2014. For the first six months of 2015, gross margin was 57%, compared to 44% in the first six months of 2014. The improvement over 2014 reflects higher sales from our proprietary biopreservation media products as compared to the second quarter of 2014, with improved utilization of our manufacturing facility and overhead costs. In addition, the second quarter and six months ended June 30, 2015 included \$0.1 million and the second quarter and six months ended June 30, 2014 included \$0.1 million and \$1.1 million, respectively, of low margin contract-manufacturing revenue.

Consolidated net loss attributable to BioLife for the second quarter of 2015 was \$1.0 million or \$0.08/share, compared to a net loss of \$0.9 million or \$0.07/share in the second quarter of 2014. For the first six months ended June 30, 2015 consolidated net loss attributable to BioLife was \$2.0 million or \$0.17/share compared to \$1.4 million or \$0.16/share in the same period in 2014. The increase in the loss is primarily the result of lower contract manufacturing revenue in the first quarter of 2015 compared to 2014 and increased headcount and spending related to development and launch activities of our biologistex joint venture.

Product Innovation: the evo™ smart shipping container, designed and manufactured by SAVSU and marketed by BioLife, was the silver award recipient at the recent Medical Design Excellence Awards competition for the category Medical Product Packaging, Graphic Instructions, and Labeling Systems.

**Product Validation:** a new clinical article citing the use of the Company's CryoStor cryopreservation freeze media with a dendritic cell based vaccine was published in the journal Oncotarget.

**Customer Adoption:** Management believes that BioLife products are now embedded in an estimated 200 pre-clinical validation projects and human clinical trials for new cell and tissue-based regenerative medicine products and therapies. A significant number involve CAR-T cells and other types of T cells and mesenchymal stem cells targeting blood cancers, solid tumors and other leading causes of death and disability.

Cardio3 BioSciences, a leader in engineered cell therapy with clinical programs initially targeting indications in cardiovascular disease and oncology, has embedded the Company's clinical grade CryoStor cryopreservation freeze media in its ongoing Congestive Heart Failure Cardiopoietic Regenerative Therapy (CHART-1) phase III clinical trial in Europe and Israel and the pending CHART-2 phase III clinical trial to be conducted in the United States.

Cord Blood Registry (CBR®), the world's largest newborn stem cell company, announced the adoption of BioLife's CryoStor clinical grade cryopreservation freeze media in its process for cryogenic storage of umbilical cord tissue stem cells.

Several new customers disclosed the use of the Company's CryoStor and HypoThermosol biopreservation media products in pre-clinical validation projects and clinical trials at the recent International Society for Cellular Therapy (ISCT) conference as follows:

GSK – Overcoming automation and formulation challenges in the manufacture and distribution of next generation ex vivo gene therapy products.

HemaCare Bioresearch Products & Services – Cryopreserved Leukopaks (LP) Maintain Cell Viability & Functionality.

MaSTherCell (for their customer Imcyse) – Technology Transfer and Process Development for an Autologous Cell Therapy Against Multiple Sclerosis.

RoosterBio – poster: Cryopreserved hMSC maintain comparable in vitro functional activity compared to fresh hMSC.

## Results of Operations

Our revenue, results of operations and cash balances are likely to fluctuate significantly from quarter-to-quarter. These fluctuations are due to a number of factors, specifically the progress of our customers' clinical trials, where the pace of enrollment affects customer orders for our products. The majority of our net sales come from a relatively small number of customers and a limited number of market sectors. Each of these sectors is subject to macroeconomic conditions as well as trends and conditions that are sector specific. Any weakness in the market sectors in which our customers are concentrated could affect our business and results of operations.

## Comparison of Results of Operations for the Three and Six Month Periods Ended June 30, 2015 and 2014

Percentage comparisons have been omitted within the following table where they are not considered meaningful.

### Revenue and Gross Margin

	Three Month Period Ended			% Change
	June 30,			
	2015	2014		
Revenue:				
Core product sales	\$ 1,433,425	\$ 1,076,780		33%
Contract manufacturing services	63,334	135,120		(53)%
Total revenue	1,496,759	1,211,900		24%
Cost of sales	678,111	666,580		2%
Gross profit	818,648	545,320		50%
Gross margin %	55%	45%		
	Six Month Period Ended			% Change
	June 30,			
	2015	2014		
Revenue:				
Core product sales	\$ 2,910,600	\$ 2,209,025		32%
Contract manufacturing services	86,881	1,067,905		(92)%
Total revenue	2,997,481	3,276,930		(9)%

Cost of sales	1,296,210	1,828,221	(29)%
Gross profit	1,701,271	1,448,709	17%
Gross margin %	57%	44%	

Core Product Sales. Our core products are sold through both direct and indirect channels to customers in the regenerative medicine, biobanking and drug discovery markets. Sales of our core proprietary products in the three and six months ended June 30, 2015 increased compared to the same period in 2014, due primarily to a 40% and 36%, respectively, increase in proprietary product liters sold during the periods and revenue growth of 63% year-to-date over the same period in 2014 from customers in the regenerative medicine segment. We expect to see continued growth in adoption and use of our proprietary biopreservation media products, and estimate 20% - 30% growth in core product revenue in 2015 compared to 2014. Additionally, we expect to report revenue from our biologistex Cold Chain Management service in the third quarter.

**Contract Manufacturing Services.** In the three and six months ended June 30, 2015, contract manufacturing revenue was the result of process validation work performed for one customer and sales of certain raw materials related to this customer. In 2014, contract manufacturing services represented sales of product to one significant different customer. The contract with this customer was terminated in May 2014, and we do not expect any future revenue from this customer.

**Cost of Sales.** Cost of sales consists of raw materials, labor and overhead expenses. Cost of sales in the three months ended June 30, 2015 increased compared to the same period in 2014 due to increased sales of our proprietary products. Cost of sales in the six months ended June 30, 2015 decreased compared to the same periods in 2014 due primarily to the reduction in contract manufacturing services revenue and costs related to the manufacture of this product, offset by increased sales of our proprietary products.

**Gross Margin.** Gross margin as a percentage of revenue was 55% and 57% in the three and six months ended June 30, 2015 compared to 45% and 44% in the three and six months ended June 30, 2014. The increase was due to an increase in core product revenue and the reduction in low margin contract manufacturing revenue. For the full year, we expect gross margin to be in the range of 55% to 60%.

**Revenue Concentration.** In the three and six months ended June 30, 2015, we derived approximately 15% and 10% of our product revenue from one customer. In the three and six months ended June 30, 2014, we derived approximately 11% and 33%, respectively, of our product revenue from our relationship with one contract manufacturing customer. No other customer accounted for more than 10% of revenue in the three and six months ended June 30, 2015 or 2014.

#### Operating Expenses

Our operating expenses for the three and six month periods ended June 30, 2015 and 2014 were:

	Three Month Period Ended June 30,		
	2015	2014	% Change
Operating Expenses:			
Research and development	\$ 301,334	\$ 192,778	56%
Sales and marketing	642,490	270,616	137%
General and administrative	1,030,701	969,799	6%
Operating Expenses	1,974,525	1,433,193	38%
% of revenue	132%	118%	

	Six Month Period Ended June 30,		
	2015	2014	% Change
Operating Expenses:			
Research and development	\$ 623,499	\$ 360,065	73%
Sales and marketing	1,142,745	512,016	123%
General and administrative	2,251,406	1,833,542	23%
Operating Expenses	4,017,650	2,705,623	48%
% of revenue	134%	83%	

**Research and Development.** Research and development expenses consist primarily of salaries and other personnel-related expenses, consulting and other outside services, laboratory supplies, and other costs. We expense all research and development costs as incurred. Research and development expenses exclude the costs associated with development of customized internal-use software systems. Research and development expenses for the three and six months ended June 30, 2015 increased compared to the three and six months ended June 30, 2014, due primarily to higher personnel costs, with the addition of personnel in the fourth quarter of 2014, and salary increases that were effective on January 1, 2015.

**Sales and Marketing.** Sales and marketing expenses consist primarily of salaries and other personnel-related expenses, consulting, trade shows and advertising. The increase in the three and six months ended June 30, 2015 compared to the same periods in 2014 was due primarily to higher personnel costs, with the addition of personnel in 2014 and 2015 and salary increases that were effective on January 1, 2015, and initial marketing costs related to our new biologistex service.

**General and Administrative Expenses.** General and administrative expenses consist primarily of personnel-related expenses, non-cash stock-based compensation for administrative personnel and members of the board of directors, professional fees, such as accounting and legal, corporate insurance, and participation fees to SAVSU related to the biologistex joint venture. We did not record any participation fees to SAVSU in the second quarter of 2015. The increases in general and administrative expenses in the six months ended June 30, 2015 compared to the same period in 2014 includes approximately \$0.2 million in participation fees to SAVSU, recorded in the first quarter of 2015. The increase in other general and administrative costs in the three and six months ended June 30, 2015 compared to the same periods in 2014 were due to higher personnel costs with the addition of personnel in 2014 and salary increases that were effective on January 1, 2015 and higher corporate costs, including insurance, taxes, director fees and consulting fees.

#### Other Income (Expenses)

Interest Expense. The reduction in interest expense in the three and six months ended June 30, 2015 compared to the same periods in 2014 is due to the conversion to equity of all outstanding notes and interest through March 25, 2014.

Amortization of Deferred Financing Costs. Amortization of deferred financing costs represented the cost of warrants issued which were amortized over the life of the debt. In connection with the termination of the note facility agreements in March 2014, we recorded \$101,852, the remaining unamortized costs, as an adjustment to additional paid in capital.

#### Liquidity

We expect to end the year with approximately \$4 million in cash, cash equivalents and short term investments. The estimated use of cash in 2015 includes substantial costs related to the development and marketing launch of our biologistex Cold Chain Management service. We anticipate that our current level of cash and cash equivalents is sufficient to meet our liquidity needs for the foreseeable future and do not expect a need to raise operating capital in 2015 or 2016.

We expect to have ongoing cash requirements which we plan to fund through total available liquidity and cash flows generated from operations. Our future uses of cash, which may vary from time to time based on market conditions and other factors, are centered on growing our core business, launching and deploying our biologistex service, and continuing to strengthen our balance sheet and competitive position.

On June 30, 2015, we had \$6.9 million in cash, cash equivalents and short term investments, compared to cash and cash equivalents and short term investments of \$9.9 million at December 31, 2014.

#### Net Cash Used In Operating Activities

During the six months ended June 30, 2015, net cash used in operating activities was \$2.5 million compared to \$1.8 million for the six months ended June 30, 2014. Cash used in operating activities increased primarily due to the use of cash to fund a higher net loss and cash used by changes in operating assets and liabilities during the period ended June 30, 2015 compared to the same period in 2014.

#### Net Cash Provided by/Used in Investing Activities

Net cash provided by investing activities totaled \$3.8 million during the six months ended June 30, 2015, which was the result of sales and maturities of short term investments, net of purchases of short term investments and purchases of equipment and costs associated with internal use software development during the quarter. Cash used in investing activities was \$6.2 million for the six months ended June 30, 2014. The Company used \$0.3 million and \$6.1 million to purchase short term investments classified as available-for-sale in the periods ended June 30, 2015 and 2014, respectively, and received \$4.7 million in proceeds from sales/maturities in the period ended June 30, 2015 and none in the 2014 period. In addition, during both periods, cash was used in investing activities related to the purchase of equipment and in the six months ended June 30, 2015, \$0.5 million was used in the development of software for internal use.

#### Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$80,000 and \$13.7 million in the six months ended June 30, 2015 and 2014, respectively. Net cash provided by financing activities during the six months ended June 30, 2015 was the result

of proceeds received from employee stock option exercises. Net cash provided by financing activities in the six months ended June 30, 2014 was primarily the result of proceeds received from the registered public stock offering completed on March 25, 2014, net of placement agent fees and offering costs.

Upon conversion of all of our outstanding notes and interest to equity on March 25, 2014, we terminated the facility agreements.

#### Off-Balance Sheet Arrangements

As of June 30, 2015, we did not have any off-balance sheet arrangements.

#### Critical Accounting Policies and Significant Judgments and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements as well as reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate estimates, including, but not limited to those related to accounts receivable allowances, determination of fair value of share-based compensation, contingencies, income taxes, useful lives and impairment of intangible assets and internal use software, and expense accruals. We base our estimates on historical experience and on other factors that we believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

Our critical accounting policies and estimates have not changed significantly from those policies and estimates disclosed under the heading “Critical Accounting Policies and Significant Judgments and Estimates” in Part II, Item 7, “Management’s Discussion and Analysis of Financial Conditions and Results of Operations” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed with the SEC.

#### Contractual Obligations

We previously disclosed certain contractual obligations and contingencies and commitments relevant to us within the financial statements and Management Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the SEC on March 12, 2015. There have been no significant changes to these obligations in the three months ended June 30, 2015. For more information regarding our current contingencies and commitments, see note 10 to the consolidated financial statements included above.

#### Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

#### Item 4. Controls and Procedures

**Evaluation of Disclosure Controls and Procedures.** We maintain disclosure controls and procedures that are designed to ensure that material information required to be disclosed in our periodic reports filed under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms and to ensure that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer as appropriate, to allow timely decisions regarding required disclosure. During the quarter ended June 30, 2015, we carried out an evaluation, under the supervision and with the participation of our management, including the chief executive officer and chief financial officer, as required by the rules and regulations under the Exchange Act, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of June 30, 2015, our disclosure controls and procedures were effective.

**Changes in Internal Control over Financial Reporting.** There have been no changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2015 that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

**Limitations on Effectiveness of Control.** Our management, including our chief executive officer and chief financial officer, does not expect that our disclosure controls and procedures or our internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our Company have been detected.

## PART II: Other Information

#### Item 6. Exhibits

See accompanying Index to Exhibits included after the signature page of this report for a list of exhibits filed or furnished with this report.



SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: August 6, 2015

BIOLIFE SOLUTIONS, INC.  
/s/ Daphne Taylor  
Daphne Taylor  
Chief Financial Officer  
(Duly authorized officer and  
principal  
financial and accounting officer)

BIOLIFE SOLUTIONS, INC.

INDEX TO EXHIBITS

Exhibit No.	Description
10.1	Amended & Restated 2013 Performance Incentive Plan (included as Appendix A to the Registrant's Definitive Proxy Statement filed on March 24, 2015 and incorporated herein by reference)
10.2	Board of Directors Services Agreement entered into May 4, 2015 by and between the Registrant and Raymond W. Cohen (included as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 5, 2015 and incorporated herein by reference)
10.3	Board of Directors Services Agreement entered into May 4, 2015 by and between the Registrant and Thomas Girschweiler (included as Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on May 5, 2015 and incorporated herein by reference)
10.4	Form of Board of Directors Services Agreement entered into with other non-employee directors (included as Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on May 5, 2015 and incorporated herein by reference)
<u>31.1</u>	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
<u>31.2</u>	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
<u>32.1</u>	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
<u>32.2</u>	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002